APR/ 1743

Patent Application
Attorney Docket No. PC11851A

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By Sarah J. Delaney
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Kenneth C. Waterman :
SERIAL NO.: 10/099,646 : Examiner: Latoya I. Cross
FILED: March 15, 2002 : Art Unit: 1743
FOR: Dispensing Unit for Oxygen-Sensitive Drugs

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Madam or Sir:

RESPONSE UNDER RULE 1.111

Responsive to the Office Action of October 19, 2004, reconsideration and reexamination of this application are requested in view of the following comments.

The present invention is directed to a pharmaceutical packaging means having an oxygen-absorber incorporated therein. The packaging allows for dispensing a single unit dose of an oxygen-sensitive drug without exposing the remaining unit dosages to oxygen.

The claims pending in this application number 1-3, 8-18 and 20-21.

Claims 1, 11-18, 20 and 21 have been rejected under 35 USC 103(a) as being obvious over U.S. 5,682,626 to Green et al. in view of U.S. 6,139,770 to Katsumoto et al. Claims 1-3, 8-10, 20 and 21 have been rejected under 35 USC 103(a) as being unpatentable over U.S. 6,279,736 to Hekal et al. in view of Katsumoto et al. The Examiner's comments have been carefully considered, and the rejections are respectfully traversed.

The Examiner is of the opinion that Green et al. teach a package for containing drugs or medicaments wherein the shelf-life of the drugs is increased. The Examiner is of the further opinion that Green et al. differ from the present invention in that there is no disclosure of using UV activated oxygen absorbers and there is no disclosure of specific shelf-life ability of the packaging materials. Applicant respectfully disagrees.

Green et al. disclose a method for forming and packaging an iontophoretic patch in an inert atmosphere. The disclosure actually concerns transdermal patches, and requires the packaging be done in an inert atmosphere. See, for example Column 2, lines 57-59, and Column 3, lines 19-23. Such assembly is expensive and generally does not lead to very low oxygen head-space levels, as discussed in the instant specification at page 6, lines 25-31. With regard to the recitation of epinephrine, dobutamine and dopamine in Green et al., it is respectfully pointed out to the Examiner that the transdermal patches of Green et al., are not solid pharmaecutical dosage forms as required by Applicant.

The transdermal patches of Green et al. are totally unrelated to the instant invention that stabilizes solid oral dosage forms from oxidation.

The oxygen scavenging system of Katsumoto et al. is part of the art that is discussed at page 10, lines 5-8 of the instant specification. The scavenging system of Katsumoto et al. was developed in response to the food industry's goal of having longer shelf-life for packaged food. See Column 1, lines 14-16. Katsumoto et al. developed UV light activated thermal formable plastic. The purpose was to use the plastic in multi-layered food andbeverage packages to extend shelf-life. Katsumoto et al. do not teach or suggest the incorporation of oxygen scavengers in a blister, as required by Applicant. Moreover, the only reference to a pharmaceutical application is as part of a laundry list of potential uses.

Hekal's disclosure is directed to moisture absorption and carbon absorption of odors. See column 8, lines 31-43 It is clear that Hekal is disclosing the use of a desiccant (in connection with moisture removal), which has nothing to do with Applicant's invention.

Hekal discloses a process for providing moisture permeable channels so that moisture can reach desiccants embedded in the blister packaging. In contrast, Applicant's invention does not require such channels since oxygen is quite permeable. The Hekal blister package becomes active from deposition of the material in the blister. In practical terms, Applicant's blister can be formed and stored under ambient conditions and activated immediately before use. Hekal requires the deposition of absorbing material right before use or storage in an inert atmosphere. Hekal's deposited material may come into direct contact with the active drug which may lead to safety and/or toxicity issues.

It is submitted the rejection under 35 USC 103 is based on speculation or the unsupported opinion of the Examiner derived by hindsight knowledge of Applicant's specification since there is no teaching or suggestion in the references to make the combinations alleged by the Examiner to be obvious. The Examiner is suggesting an "obvious to try" concept. But, such a concept does not render Applicant's invention as presently claimed unpatentable.

Because chemistry is often an empirical science, it is easy to characterize inventions in the field as being the result of "routine testing" or having been "suggested". However, while obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art" In re Keller, 208 USPQ 871, 881 (CCPA 1981), it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, or suggestion supporting the combination" ACS v. Montefiore, 221 USPQ 929, 933 (Fed. Cir. 1984).

Accordingly, Applicant respectfully submits that all of the claims as presently amended are clearly patentable over Hekal and Green et al. and the rejections under 35 USC 103 have been overcome. Withdrawal of the rejections is requested.

This application is believed to be in condition for allowance. Favorable consideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§ 1.16 and 1.17, or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

Date: November 15, 2004

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